

# Contract Concept Review: Laboratory Studies for the NTP to Evaluate Toxicity Following Early Life Exposure to Chemicals

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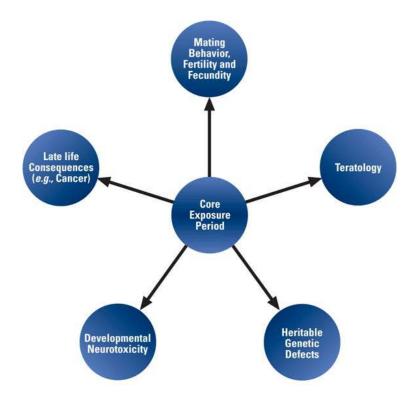
## **Background**

- NTP actively investigates adverse reproductive and developmental effects in rodents as part of its broad mandate to characterize toxicity of agents of public health concern
- Currently 1 in 3 nominations requires reproductive and developmental toxicity testing
- Backlog of 30 compounds for these types of studies
- This proposed contract will:
  - Allow NTP to increase its capacity to conduct these studies
  - Allow highly flexible study designs to evaluate effects of early life exposures over multiple life stages



### **Need for Reproductive and Developmental Testing**

- Adverse effects of chemical exposures during early life stages of gestation and the perinatal period continue to be an area of concern for the scientific community and the general public
- 5-10% of couples desiring children have problems achieving pregnancy; 35-50% of pregnancies are not completed
- 3-5% of newborns have birth defects
- 25% increase in diagnosis of invasive childhood cancers since 1975
- 3-7% of school-aged children diagnosed with ADHD
- Etiology of these problems is largely unknown
- Fetal and early postnatal life constitutes a vulnerable time for development and disturbing critical developmental processes can lead to functional deficits and increased disease risks later in life





### **NTP Studies**

- Comprehensive battery of evaluations to examine multigeneration effects and the spectrum of life stages is planned
- Study designs will be flexible to incorporate chemical-specific needs
- Study designs will include dosing through gestation and lactation periods and may be extended for 90-days, one year or lifetime, depending on test article-specific needs
- Endpoints measured will be flexible depending on test article needs and include reproductive parameters, developmental assessments and other assessments to evaluate adverse effects manifested later in life
- Capability to conduct "womb to tomb" assessments



# Request

- NTP has a need for increased flexibility in study designs and increased capacity to conduct studies to evaluate adverse effects of exposure to chemicals during early life stages
- NTP seeks the BSC's approval to use a contract mechanism for this work